

Appl. No. 10/807,974  
Dated: August 17, 2009  
Reply to Office action of May 15, 2009

### **REMARKS**

Claims 1-9, 20-26, 34-38, and 73-76 were before the Examiner for consideration, Claims 10-19, 27-33, and 39-72 having been previously withdrawn. In this paper, Claims 1, 75, and 76 have been amended, Claim 73 has been canceled without prejudice, and no new claims have been added. Accordingly, Claims 1-9, 20-26, 34-38, and 74-76 remain before the Examiner for consideration. No new matter has been added with these amendments.

### **Summary of the Office Action**

In the Office Action, previously submitted Claim 73 and 74 were indicated to be directed to an invention distinct from the invention originally claimed and withdrawn by the Examiner. Claims 1-9, 20-26, 34-38, 75, and 76 were rejected under 35 U.S.C. § 112 to as failing to comply with the written description requirement. Claims 1-9, 20-24, 34-38, 75, and 76 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine (US Patent No. 6,520,939), in view of Steigerwald (U.S. Patent No. 4,895,346). Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine in view of Steigerwald further in view of Green et al. (U.S. Patent No. 6,497,716). For at least the reasons discussed below, Applicant respectfully traverses these rejections.

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#### **Regarding Claims 73 and 74**

As noted above, Claim 73 and 74 were withdrawn by the Examiner and indicated to be directed to independent or distinct inventions from the inventions originally claimed. In order to expedite prosecution on the currently-pending claims, Applicant has canceled Claim 73 without prejudice. Applicant respectfully traverses this withdrawal with respect to Claim 74, as applicant notes that a septum seal comprising an elastomeric sheet with a generally conical profile, as recited therein, is shown at least in Figures 6, 7, and 8, corresponding to the species elected for prosecution. Accordingly, Applicant respectfully requests the consideration of Claim 74 in a subsequent non-final Office Action.

#### **Regarding the Rejections under 35 U.S.C. §112**

As noted above, Claims 1-9, 20-26, 34-38, 75, and 76 were rejected under 35 U.S.C. § 112 to as failing to comply with the written description requirement. Specifically, in the Office Action, it was indicated that the recited "aperture" was not described in the specification as filed. Applicant notes that this rejection appears to be improper as there are numerous references in the specification as filed to an orifice, hole, and piercing, and it is well established that there is no requirement for an *in haec verbae*, that is, word-for-word, correspondence between the specification as filed and the claim terminology (see, e.g., M.P.E.P. 2163.02, stating that the "subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in

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order for the disclosure to satisfy the description requirement.”). However, in order to expedite prosecution on the presently pending claims, Applicant has amended Claims 1, 75, and 76 to recite an “orifice” rather than an aperture. Applicant notes that the specification as filed contains numerous references to an “orifice.” (See, e.g., paragraph [0066] of U.S. Patent Application Publication No. 2005/0216028, corresponding to the present Application). Accordingly, Applicant respectfully submits that the rejections under 35 U.S.C. §112 are no longer applicable to the pending claims, and Applicant respectfully requests the withdrawal of these rejections.

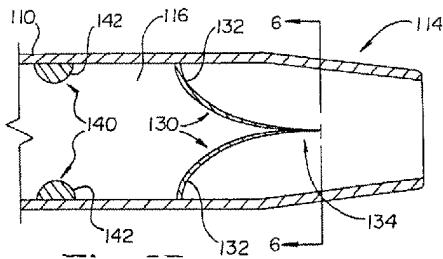
**The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine and Steigerwald.**

As noted above, in the Office Action, Claims 1-9, 20-24, 34-38, and 75-76 were rejected under 35 U.S.C. § 103(a) as being anticipated by Lafontaine in view of Steigerwald. For at least the reasons discussed below, Applicant respectfully traverses these rejections.

Lafontaine relates to a hemostasis valve for use with vascular introducer sheaths, catheters, Y-adapters, and the like. (Lafontaine, col. 1, lines 6-9). As illustrated in Figure 5A, reproduced below, Lafontaine describes an introducer sheath including an active hemostasis valve 130 and a passive hemostasis valve 140. (Lafontaine, col. 4, lines 6-7). The active hemostasis valve 130 comprises a plurality of leaflets or flaps 132. (Lafontaine, col. 4, lines 30-31). The passive hemostasis valve

140 is normally open to allow devices to freely pass therethrough, and comprises a flexible polymeric O-ring sized to create either an interference fit or a gap fit with a device inserted therethrough. (Lafontaine, col. 4, lines 47-64).

*Fig. 5A*



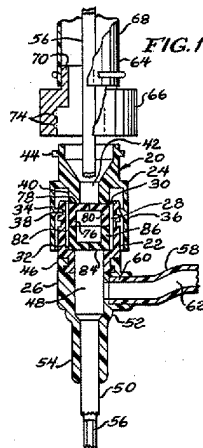
Lafontaine teaches away from using a “gasket” seal with the device disclosed therein. In connection with the background to the Lafontaine device, Lafontaine does describe a “gasket” having a hole or slit therethrough. (See, e.g., Lafontaine, col. 1, lines 27- 41, Figures 2A, 2B). However, Lafontaine describes these gasket configurations only in relation to admitted prior art vascular access systems that, unlike the access device recited in Claim 1, do not include another seal. Furthermore, Lafontaine emphasizes perceived undesirable performance characteristics of each of these gasket configurations to assert the desirability of the O-ring. (Lafontaine, col. 1, lines 42-55). Thus, Lafontaine teaches away from using one of the described gaskets as either an active hemostasis valve or a passive hemostasis valve in the described surgical access device.

Steigerwald relates to a valve assembly 20 having a hollow body member 22, a compression member 24, and two elastic valve members received in a cavity 28 at the

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proximal end of the body member 22. (Steigerwald, col. 2, lines 32-35, col. 3, lines 13-19). The compression member 24 has internal threads to cooperate with threads of the body member 22 in order to adjust the compression member to seal the first and second valve members 76, 82. (Steigerwald, col. 2, lines 42-52, col. 4, lines 29-44).

Figure 1 of Steigerwald, reproduced below, illustrates Steigerwald device.



In contrast to the Lafontaine and Steigerwald devices, Claim 1 relates to a surgical access device comprising, among other recitations, an elongate tubular member, a septum seal integrally formed at the distal end of the tubular member, and a zero seal disposed at the distal end of the tubular member and distal to the septum seal. The septum seal comprises, among other limitations, "an elastomeric sheet and an orifice through the elastomeric sheet."

-- *The Applied Combination of References Fails to Disclose All of the Recitations of Claim 1.*

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As discussed above, Lafontaine fails to disclose a septum seal as recited in Claim 1. Rather, Lafontaine describes an O-ring positioned in an elongate shaft to provide appealing under certain conditions. Steigerwald fails to remedy to the deficiencies of Lafontaine with respect to Claim 1. For example, Steigerwald fails to disclose a septum seal "integrally formed" at the distal end of a tubular member. Rather, as discussed above, in the Steigerwald device, two separate valve members are positioned within a cavity at the proximal end of a valve assembly. The valve members are compressible with respect to the cavity of the valve assembly by a compression member. Thus, the Steigerwald valve members are not "integrally formed," nor positioned at the distal end of the tubular member, as recited in Claim 1.

*-- One Skilled in the Art Would Be Dissuaded by Lafontaine from Incorporating a Valve Member from the Steigerwald Device Therein.*

As discussed above, Lafontaine fails to disclose all of the elements of the recited surgical access device. For example, Lafontaine fails to disclose a septum seal comprising an elastomeric sheet and an orifice through the elastomeric sheet, as is recited in Claim 1. Furthermore, one skilled in the art would be dissuaded by Lafontaine from modifying the device therein to include a valve member as described in the Steigerwald. Rather, as discussed above, Lafontaine teaches away from the use of a disk-shaped "gasket" similar to the valve members of Steigerwald, repeatedly emphasizing the perceived disadvantages of these valve members.

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*-- This Suggested Combination of Lafontaine with Steigerwald Would Result in a Non-Operative Device.*

Furthermore, one skilled in the art would be dissuaded from modifying Lafontaine to include a valve member as described in Steigerwald as such a device would be non-operative. As discussed above, the Steigerwald device includes two valve members disposed in a cavity at a proximal end of a valve assembly. Steigerwald indicates that in order for the valve members to seal effectively in all conditions, a compression member threadedly cooperating with the valve assembly must be adjusted to compress the valve members. However, in the Lafontaine device, the active and passive hemostasis valves 130, 140 are described and illustrated as being in a distal portion of an elongate shaft of an introducer sheath. (See, e.g., Lafontaine, Figures 3, 5A, 5B). Accordingly, the Steigerwald compression member, required for operation of the Steigerwald valve members could not be positioned in the Lafontaine device in a location where it would be adjustable, thus rendering the resultant combined device nonoperative. Thus, one skilled in the art would be dissuaded from making the combination suggested in the Office Action as there would be no reasonable expectation of success with the resulting device.

Accordingly, for at least the reasons discussed above, Claim 1 is distinguishable over the applied art. Claims 2-9, 20-24, 34-38, and 74-76 depend from Claim 1 and

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recite additional novel and nonobvious limitations thereon. Therefore, Claims 2-9, 20-24, 34-38, and 74-76 are distinguishable over the applied art for at least the reasons discussed above with respect Claim 1.

**The Recited Subject Matter Is Distinguishable over the Applied Combination of Lafontaine, Steigerwald, and Green.**

As noted above, Claims 25 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lafontaine and Steigerwald in view of Green et al. Claims 25 and 26 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. As discussed above, the applied combination of Lafontaine and Steigerwald fails to disclose or suggest all of the limitations of Claim 1. Green appears to have been relied on in the Office Action solely for its asserted disclosure of a specific shape of certain portions of a placement device. Green thus fails to disclose or suggest the deficiencies of Lafontaine and Steigerwald with respect to Claim 1.

Accordingly, for at least the reasons discussed above, the applied combination of references fails to disclose or suggest all of the limitations of Claim 1, from which Claims 25 and 26 depend. Therefore, at least for the reasons that Claim 1 is distinguishable over the applied combination of references, Claims 25 and 26 are distinguishable over the applied combination of references.



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### **Conclusion**

For at least the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowability is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

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The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, John F. Heal, at (949) 713-8283 to resolve such issues promptly.

Respectfully Submitted,

APPLIED MEDICAL RESOURCES

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